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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,717	09/17/2003	Jonathan Fanger	101896-0207	4656

21125 7590 11/23/2005

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT PAPER NUMBER

3738

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/665,717

Applicant(s)

FANGER ET AL.

Examiner

Robert W. Amareld, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/22/04, 9/20/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: **The drawings do not include any of the referenced figure numbers within the specification, the drawing components will be interpreted at the examiner's discretion.** The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **"ball and dent"** must be shown or the feature(s) canceled from the claim(s), **claim 8, additionally "push button mechanism" in claims 12, 14, 24 & 26 is not shown.** No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim incorrectly claims itself for dependency, it is impossible to discern which dependency claim 26 is intended to rely on. The dependency could be any of claims 21-25, 21 being where the stop member originates. The invention will be interpreted at the examiners discretion for further examination purposes.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-11, 13, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson (US Pat # 3540322). Swanson discloses a drill having an internal spring (19) biased elongate shaft (4) with a proximal end adapted to mate with driver mechanism (5,6) and a cutting drill bit end capable of bone preparation, an slidable/adjustable elongate sleeve (11, column 1, lines 51-53) with a lower stepped region (23) with a diameter less than that of the upper stepped portion (11) which could fit into the lumen of a drill guide or plate, where the sleeve effectively aligns the shaft,

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the sleeve being a spot member disposed around the shaft to limit penetration. The shaft includes a flange (collar 17, also a stop member), which is fixed to the shaft by a screw (18), the screw being a pin that extends through the sidewall, and prevents removal of the shaft from the sleeve, the screw and collar also serve to maintain the sleeve in a predetermined position, with free rotation of the collar within the sleeve (column 1, lines 57-58), the outer sleeve (10) and arm (9) also aid in maintaining position of the sleeve. The hollow tube is threaded (23, column 2, line 1) and mates with the threads of piece 24, which are formed around the shaft.

Claims 1, 7 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinz-Jurgen (Pat# DE 3800482). Heinz-Jurgen discloses a shaft (4) adapted to mate with a driver mechanism and bone preparation element (2), having hollow aligning sleeve (5) slidably disposed along the shaft, the shaft having a stepped region at the end (6), the step being the tapered portion, where a portion of the sleeve has a lesser diameter than the main portion and can be fit into a drill guide or plate. The assembly comprises the engagement member (20), which temporarily maintains the sleeve in a predetermined position relative to the shaft, the engagement member comprising a ball (16) and a dent (12).

Claims 1, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Davison (US Pat# 4710075). Davison discloses a shaft (12, 16) with engaging end (24) and drilling end (14), an elongate hollow sleeve (26) having stepped regions (30, 29) lower region 30 having a smaller diameter than center region 29 which could fit within the lumen of a guide or a plate and could help to align the shaft with these structures.

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The sleeve (26) also contains the stop member (44, plunger) to limit penetration of the shaft where the plunger acts on the proximal surface of the sleeve to limit penetration of the shaft. Plunger (44) is also a hollow tube, which becomes a push button when combined with the spring (60) and is slidably adjustable along the shaft to a plurality of positions. The button (44) ridge (48) engages one of the plurality of dents (20, groove) and allows adjustment of the position of the stop member. The ridge (48) is a singular thread, which engages the singular threads (20) along the surface of the shaft (16), the ridge being part of the plunger (44), which is part of the hollow sleeve (26).

Claims 1, 9-11, 13, 15, 21-23, 25, 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspar (US Pat# 5669915). Caspar discloses a drill guide (1) adapted to be aligned with at least one bore on bone plate (29), a shaft drilling tool (12) with a bone preparation element on tip (Figure 2) that is screwable to a sleeve or tube (column 1, lines 5-8) screwable objects inherently having threads, and an elongate hollow sleeve (7) disposed around the shaft that fits within the lumen (14) of the guide, the sleeve having grip part (19) with a diameter larger than that of the inner diameter of the guide lumen or the sleeve lumen, where the sleeve is effective at aligning the shaft with a lumen of the guide and bore of the plate (29, Figures 1 & 2) and at least one lumen in the drill guide has a length substantially the same as that of the sleeve (Figure 2). Grip part (19) serves as a stop member and stepped region, being part of a hollow tube, to limit penetration of the shaft and is slidably adjustable to a plurality of position with depth scale (17), where the stop member acts on a proximal portion of the sleeve to limit penetration. Caspar also discloses fastening elements (column 3, lines 4-

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7) for use with the plate (29), screws inherently having a head and substrate-engaging portion and may be of size to less than the diameter of the drill guide lumen.

Additionally, with further respect to claims 1 & 9-11 the sleeve (7) may be interpreted as the shaft as it has bone a bone preparation element (9, Figure 1) with end (19) adapted to mate with a driver mechanism, and the guide (1) may be interpreted as the sleeve which has a threaded portion (13) to mate with the threaded screw in section (15) of the shaft.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspar (US Pat #5669915) in view of Swanson (US Pat# 3540322) Both Caspar and Swanson are explained Supra. Caspar discloses a drill shaft (12), sleeve (7), guide (1) and flange (19, 21). Caspar, however, lacks a spring-bias. Swanson teaches the spring (19) bias such that the shaft is retracted into the sleeve without sufficient force to do otherwise. It would have been obvious to one of ordinary skill in the art at the time of the inventions to use the spring bias, as taught by Swanson with the devices of Caspar such that it provides the ability to maintain the drill shaft within the sleeve in the absence of a force to oppose the bias.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caspar (US Pat #5669915) in view of Davison (US Pat#4710075). Caspar and Davison are both described supra. Caspar discloses a drill shaft (12), sleeve (7), guide (1) and flange (19, 21). Caspar, however, lacks a push-button mechanism. Davison teaches the push button mechanism and plurality of dents. It would have been obvious to one of ordinary skill in the art at the time of the inventions to use the drilling jig, as taught by Caspar with the push button adjustable drill gauge of Davison such that it provides the ability to more quickly and easily effect the adjustment of the stop member and drill guide.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilson, US Pat # 5197967- instrument for cutting holes; Zwirnmann, US Pat# 6951562- adjustable tap; Zech, US Pat# 6110178 – apparatus for making bores; Larson, US Pat# 5948000- system for suture placement; Erickson, US Pat# 5649793- self centering drill tool; Neuhauser, US Pat# 4273117- bone drill; Martin, US Pat# 854956-surgical instrument; Levedahl, US Pat# 1831813- attachment for drills and Geistauts, US Pat# 3128768- surgical drill.

Additionally, please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. The disclosed invention also falls within the drill art under class 408 "CUTTING BY USE OF ROTATING AXIALLY




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MOVING TOOL" within one of the following subclasses 408/112, 119, 202 and has been treated as such.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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